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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,868	05/04/2001	Wei-Qiang Gao	GENENT.035C1	1085
7590 09/24/2007				
Ginger R Dreger Esq Heller Ehrman White & McAuliffe LLP 275 Middlefield Road Menlo Park, CA 94025				
			EXAMINER	
			GAMETT, DANIEL C	
			ART UNIT	PAPER NUMBER
			1647	
			MAIL DATE	DELIVERY MODE
			09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/849,868

Applicant(s)

GAO, WEI-QIANG

Examiner

Daniel C. Gamett, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/02/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-8,10-12,14,16 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-8, 10-12, 14, 16, and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. The amendments of 07/02/2007 have been entered in full. Claims 2, 4, 5, 9, 13, 15, 17, 18, are cancelled. Claims 1, 3, 6-8, 10-12, 14, 16, and 19-24 are under examination.
2. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 6-8, 10-12, 14, 16, and 19-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6017886 (Carnahan), in view of U.S. Patent 5367060, issued November 22, 1994 ('060). Applicant's arguments filed 07/02/2007 have been fully considered but they are not persuasive.
5. Contrary to Applicants' assertion (remarks, page 18) the teachings of Carnahan do not require a fusion protein including sequences from two different heregulin, Carnahan merely teaches the fusion protein as a preferred and superior form of heregulin. It has been noted in the record that Carnahan teaches that heregulin- β 1 is one of many heregulin peptides that are effective in stimulating utricular sensory epithelial cells (see figures 3 and 5; column 9, lines 55-60). The heregulins β 1, β 2, β 2-like, and β 3 are identical through the growth factor

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domain. The rejection of record holds that, in view of Carnahan, it would be obvious to the skilled artisan that any heregulin peptide that retains a significant portion of the EGF-like domain can stimulate utricular sensory epithelial cells. Applicant questions (p.17) the applicability of the Carnahan reference to the instant claim, which are not limited to utricular cells. Carnahan specifically suggests that the "peptide may also be useful to treat hearing loss in mammals, including humans, which is attributable to the degeneration of inner ear hair cells, *i.e.*, by regenerating such hair cells in association with sensory epithelium" (column 3, lines 17-20). Carnahan particularly points to supporting cells as the target of action, which in turn favors generation of hair cells (column 9, lines 31-46). Therefore, all of the target cell populations of the instant claims are taught in Carnahan. Applicant also asserts that neither reference teaches the N-terminal or C-terminal sites of the present invention, nor does either reference suggest the sites named as suitable for substitution, deletion, or insertion. However, the '060 patent does teach all of the specific residues that may be varied recited in instant claims 1, 6, and 14, (column 21, lines 10-24). The specific sites recited in instant claims 19-21 are taught in the '060 patent in the paragraph bridging columns 22-23. The '060 patent teaches that the growth factor domain ("GFD"), homologous to the EGF family is located at about residues S216-A227 to N268-R286, thereby rendering the instantly claimed boundaries for heregulin fragments obvious.

Conclusion

6. No claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ROMEO/
PRIMARY EXAMINER
ART UNIT 1647

DCG
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18 September 2007